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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,807	11/30/2001	Jay Short	DVSA-1005US	6627

20985 7590 09/30/2003

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,807	SHORT ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-131* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

Claims 1-131 are currently pending.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-14, drawn to drug delivery system comprising self-assembling peptides.

II. Claims 15-30, drawn to drug delivery system comprising self-assembling peptides encoded by polynucleotides.

III. Claims 31-37,114,115 drawn to method of producing a polypeptide polymer.

IV. Claims 38-40, drawn to method for drug delivery.

V. Claims 41,42, drawn to method of encapsulating molecule using self-assembling peptides of Group I

VI. Claims 43,44, drawn to, to method of encapsulating molecule using self-assembling peptides encoded by polynucleotides addressed Group II.

VII. Claims 45-59, 116-131, drawn to method for generating polynucleotide variant.

VIII. Claims 60,61, drawn to polynucleotide-based screening assay.

IX. Claims 62-66, drawn to conjugate of polypeptide with second component selected from antibody, polynucleotide, etc.

X. Claims 67-71, drawn to conjugate of polypeptide encoded by polynucleotides with second component selected from antibody, polynucleotide, etc.

XI. Claims 72-84, drawn to oligonucleotide probe.

XII. Claims 85-90,108 drawn to peptide composition

XIII. Claims 92,93, drawn to fiber.

XIV. Claim 94, drawn to lubricant.

XV. Claim 95, drawn to coating composition.

XVI. Claim 96 , drawn to biochip.

XVII. Claim 97, drawn to nanomechenical element.

XVIII. Claim 98, drawn to optical switch.

XIX. Claim 99 , drawn to optical waveguide.

XX. Claims 100-104, drawn to computer-readable medium and computer system containing thereof.

XXI. Claims 105-106, drawn to polynucleotide-based method of comparing sequences.

XXII. Claim 107, polynucleotide-based method of identifying features in polynucleotides.

XXIII. Claims 109-113, drawn to expression vectors and cells comprising the vector.

Where inventions are related as disclosed but are distinct as claimed, restriction may be proper. (MPEP 806). The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are drawn to different genuses of products and are considered as distinct peptides which would be expected to possess distinctly different structure (e.g., amino acid content, secondary and tertiary structure), and/or physico-chemical properties, and/or to be capable of separate manufacture and/or use. The examination of the Groups will require different searches of the US Patents and scientific literature. A reference teaching, e.g., a peptide encoded by a polynucleotide having 50% homology to polynucleotide hybridizable under low stringency conditions to polypeptide SEQ ID No. 1 would not necessarily teach peptide of SEQ ID No. 2, and

vice versa. Further, the Groups would require consideration of different enablements and patentability issues. Consequently, the correspondent methods of use V and VI, or conjugates of Groups IX, X are independent and/or distinct due to the use of different patentably distinct agents.

Claims 1,2 link inventions I and II. The restriction requirement between the linked inventions is subject to the non allowance of the linking claims, claims 1,2. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler , 44 F.2d 1211, 1215, 170 USPQ 129, 131 - 32 (CCPA 1971). See also MPEP § 804.01.

Group I and XII are drawn to different compositions having different components.

The conjugate peptides of Groups IX,X are distinct from peptides addressed in Groups I, II, respectively, as they are drawn to conjugates and therefore require additional essential structure elements not required for peptides of Group I.

Peptides addressed in Groups I, XII and oligonucleotides of Group XI are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein.

Invention XII and inventions I, XIII-XIX are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful in other applications, such as peptide synthesis, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is

the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Computer-readable medium of Group XX can contain any type of information, other than the polynucleotides addressed in Group II. Further, the structure information on polynucleotides addressed in Group II is non-functional descriptive material which does not bring distinguishing characteristics to the medium of Group XIX.

Inventions I,XII and III-V, or inventions II and VI-VII, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods III-V or VI,VII are alternate methods of using the peptides addressed in Groups I,XII or II, respectively.

Methods of Groups VII,XXI,XXII are related as independent methods of use of polynucleotides (there is no group drawn to polynucleotide itself) which are not connected in design, operation or effect.

Sequence Election Requirement Applicable to All Groups

In addition, **each Group** detailed above reads on a plurality of independent and/or patentably distinct sequences: SEQ ID Nos 1,3,5,7,9 for polynucleotides, and SEQ ID Nos. 2,4,6,8,10 for peptides. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence.**

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

The claims of the Groups are generic to a plurality of disclose patentably distinct species of peptides, or fragments thereof which encompass a plethora of different

compound species that require a burdensome classification, and/or bibliographic, manual and computer search. Depending on the Group elected, the following election of species is hereby required for the initial search for examination on merits:

- For Groups I, II: elect between full-length peptides and fragments thereof.

-For Group II: elect between full-length nucleic acid and fragments thereof (e.g., as in claim 26).

- For Group III: elect between peptides and peptides encoded by polynucleotides.

- For Group VII: elect between full-length polynucleotides and fragments thereof.

- For Group XIV: elect between 10-meres and 15-meres.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 22, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER